3/10/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone 510-337-6700

D1447B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50617

February 13, 1998

Robert Kelly, President
Anchor J Dairy
J.J. Stevinson Corporation
25079 West River Road
Stevinson, California 95374

WARNING LETTER

Dear Mr. Kelley:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on February 9, 1998 by Food and Drug Administration (FDA) Investigator Alice Blair, have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On December 18, 1997, you consigned a cull dairy cow (identified by USDA laboratory report number 283805) for sale for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm, and was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver tissue at 2.30 parts per million (ppm) and in the muscle tissue at 3.80 ppm. The tolerance level for sulfadimethoxine in the uncooked edible tissue of cattle has been established at 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows.

The Albon brand of sulfadimethoxine boluses that you used to treat your dairy cows are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(v) and are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with approved labeling. Labeling for Albon prescribes two boluses followed by one bolus per day for three to four days. The labeling also requires a seven day withdrawal period prior to slaughter for food use. Failure to adhere to the prescribed withdrawal time is likely the cause of the presence of violative levels of sulfadimethoxine in the tissues of the animal you sold for food use.

Failure to comply with the label instructions on the drugs you use to medicate your dairy cows presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to Alice A. Blair, Investigator, U.S. Food and Drug Administration, P.O. Box 1179, Stockton, California 95201-1179.

Sincerely yours,

Patricia C. Ziobro
District Director
San Francisco District

cc:

[redacted]